TRANSCRIPTION OF THE JULY 12, 2001 HEARING AT THE CAFC ON *MYLAN v. THOMPSON ET AL.*

COURT: Next case.

CLERK: 01-1257, Mylan Pharmaceuticals v. Health and Human Services

CHESLER: Good morning, Your Honor. My name is Evan Chesler and I represent the Appellant. This is an appeal from a grant of preliminary injunction and I would like to emphasize several and only several of the points that are covered at greater length in the briefs. First, the District Court made three separate findings that there was no irreparable injury here to the Movant in the absence of the entry of a preliminary injunction. The District Court did not find some injury, a little injury, it found no injury.

COURT: But correspondingly, the District Court found that it was in the public interest to do what it did.

CHESLER: Yes, it did, Your Honor. And in fact that three of the four...

COURT: If that finding was irreversible as not clearly erroneous, would that tend to negate the finding of no irreparable harm?

CHESLER: No, Your Honor, it would not. Indeed, just several months ago, this Court held in the *Amazon.com* case that its case law and all of its logic requires that two of the four prongs of the test be satisfied. Namely, the likelihood of success on the merits and irreparable injury. It does not matter what the District Court found about the public interest, it is absolutely prohibited from entering preliminary

COURT: As the functional equivalence of the standard letters threatening to sue somebody for patent infringement?

CHESLER: The answer to that question is no, because many patents are listed and not sued on. In this case, I do not dispute that there was a reasonable apprehension of being sued on this patent and we did file such a lawsuit within the 45 day window of Hatch-Waxman. So the answer to your question, Your Honor, is no but in the circumstances of this case, there would have been a justiciable controversy under the declaratory judgment standards had there been a private right of action here and had the Declaratory Judgment Act standards otherwise apply. Now, what did the District Court due when it -- let's assume, if we could for a moment -- that the trial court was right when it applied the corresponding case rule. That, in fact, the flip side of a declaration to delist a patent is a patent infringement case and you understand I say that's wrong, but let's assume it's right. What the District Court said was therefore the underlying lawsuit that Bristol could have brought would arise under 1338(a) the patent jurisdiction and therefore I have subject matter jurisdiction. Well the interesting about that, Your Honor, is that if that had been true, then we would have the statutory bar under the Hatch-Waxman statute that says until 45 days after my client receives notice that they have certified against our patent that has been listed, they may not bring a declaratory judgment action case "with respect to the patent." That's what the statute says. Now what is the District Court say having found this is a patent act case for jurisdiction about that statutory bar because there is no question under this theory -- under the Court's theory -- this is with

respect to the patent -- it says nothing. You will not find any reference to the statutory bar.

COURT: Just so I get this straight in my mind -- it's 45 day period. It's triggered by the filing of the certification.

CHESLER: It is triggered by our receipt of their notice that they are certifying against that.

COURT: Okay, that's just a little more complicated way of -- I think it's essential to say that until this certification, 45 days is irrelevant.

CHESLER: No, Your Honor, it's not. The statute does not say during the 45-day period between certification or receipt of notice and the 45 days running you may not file. That's not what it says. It says until 45 days after the receipt of the notification you may not file. Under standard statutory construction rules, that means from the beginning of the world until that day. Okay? Because what they did, Your Honor...

COURT: Okay. I understand the scheme, not what happened here.

CHESLER: I understand.